

Remarks

Entry of the foregoing and reconsideration of the application identified in caption as amended, pursuant to and consistent with the Rules of Practice in Patent Cases, and in light of the remarks which follow, is respectfully requested.

By the present amendment, claims 1-4, 6-9, 11, 15-18, and 20-21 have been amended and claim 19 has been canceled so that claims 1-11, 15-18, and 20-21 will remain pending.

Claims 2, 3, 11, 15-18 and 20-21 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. This rejection is respectfully traversed.

Claim 1 has been amended to recite that the composition is a co-ground powdered quaternary composition where the addition of glycyrrhizate as the second co-grinding auxiliary substance is the substantial aspect for the unexpected features shown by the quaternary composition of the claimed invention as compared to the ternary composition having the same components except without glycyrrhizate. Thus, the rejection of claim 2 for indefiniteness regarding the term “corresponding” is not supported, since it is now clear that the “ternary corresponding composition” is the quaternary composition without the glycyrrhizate.

As regards the rejection for indefiniteness of the term “solubility” for lacking a proper definition of the system solute/solvent/temperature, applicants submit that from a reading of the specification it is sufficiently clear that the term “solubility” is intended for water-solubility. In fact, in the “State of the art”, page 3, lines 21-23, of the present specification, the propolis “...*poor solubility in aqueous environment* ...” is mentioned. Thus, for those skilled in the art it is readily understandable that the term “solubility” is used for “aqueous solubility”. In this regard, claim 2 has been amended to recite “aqueous solubility” to more particularly point out the present invention.

The phrase “and their derivatives” has been deleted from claims 3 and 11.

Claims 15-18 have been amended to recite that the powder composition of claim 1 is combined with suitable excipients or diluents, thus providing sufficient antecedent basis for these terms. Moreover, claims 20 and 21 have been amended to recite the products that the formulation of claim 1 is made into, thus providing sufficient antecedent basis for these terms.

Accordingly, for at least the reasons noted above, claims 2, 3, 11, 15-18, and 20-21 meet the requirements of 35 U.S.C. § 112, second paragraph, for definiteness. Withdrawal of the record rejection and allowance of said claims is respectfully requested.

Claims 1-11 and 15-21, now represented by claims 1-11, 15-18, and 20-21, stand rejected under 35 USC § 103 (a), as being obvious over Aga (A: PTO- 892, 2/1/2007) in view of Mandai (US 6,005,100) and Zaffaroni (US 3,876,816) and Kasori (JP 60188036 A-abstract). This rejection is respectfully traversed.

Claim 1 has been reformulated in order to clarify the subject-matter of the invention. The inventive composition is a powdery quaternary composition wherein the active substance propolis and a hydrophilic carrier are co-ground with two auxiliary co-grinding substances, one being an amino acid and the second one being glycyrrhizate.

Motivating the rejection on the ground of obviousness with reference to the Aga teaching in view of Mandai, Zaffaroni and Kasori, the Examiner relies upon the apparent equivalence between the two different sweeteners glycyrrhizate and threalose. Although this assumption could be done in some specific circumstances in the case of the use of glycyrrhizate as a sweetening agent, this assumption is groundless for the instant-application.

In the case at issue, in fact, the claimed composition is co-ground powdered and quaternary being formed by propolis, a hydrophilic carrier, an amino acid and glycyrrhizate, wherein:

- i) the amino acid and glycyrrhizate are two auxiliary co-grinding substances;
- ii) the component glycyrrhizate is always used as the second co-grinding auxiliary substance and not for its sweetening properties; and
- iii) the addition of this second co-grinding auxiliary confers the peculiar properties of solubility to the composition of the claimed invention.

These aspects are readily apparent from the disclosure and widely supported in the specification and claims. In Table 1 unexpected results obtained with the quaternary composition of the invention as compared to the ternary composition without glycyrrhizate are shown.

Furthermore, even though both trehalose and glycyrrhizate are sweeteners, they are not obvious variants as auxiliary co-grinding substances. The first, trehalose is a simple disaccharide and the latter, glycyrrhizate is a triterpenoid glycosidic saponin, respectively. An artisan skilled in the art would not be motivated from the prior art cited, where the

glycyrrhizate is used as flavour-imparting/sweetening agent, to substitute glycyrrhizate with trehalose for the purpose of the present invention, i.e., for use as auxiliary co-grinding substances to increase solubility.

In fact, it is accepted law, that when the invention is more than the predictable use of prior art elements according to their established function, the invention is not obvious. As recently reiterated by the Supreme Court (*KSR International Co vs Teleflex*), the fact that the known elements work together in an unexpected and useful manner as noted above support the conclusion of non-obviousness.

The conclusion of obviousness by the Examiner is based upon viewing the claimed invention as merely a predictable combination of components to impart flavour/sweetness to the composition. This analysis overlooks the unexpected aspects of the claimed invention deriving from the addition of glycyrrhizate as auxiliary co-grinding substance, namely the increased solubility properties of the co-ground powdered quaternary compositions, comprising glycyrrhizate, in comparison to the corresponding ternary composition without glycyrrhizate.

Not one of the prior art references cited by the Examiner teaches or suggests that glycyrrhizate can be an auxiliary co-grinding substance, nor do they teach or suggest an expected synergistic effect between the same and an amino acid with respect to increased solubility. Therefore, one of ordinary skill in the art would not have had a *prima facie* reasonable expectation of success in producing the claimed invention.

For at least the reasons noted above, withdrawal of the record rejection of claims 1-11, 15-18, and 20-21, under 35 USC § 103 (a), as being obvious over Aga (A: PTO- 892, 2/1/2007) in view of Mandai (US 6,005,100) and Zaffaroni (US 3,876,816) and Kasori (JP 60188036 A-abstract) and allowance of said claims is respectfully requested.

Claims 1-11 and 15-21, now represented by claims 1-11, 15-18, and 20-21, stand rejected on the ground of non-statutory obviousness-type double patenting as being obvious over claims 1, 6, 9, 10, 11, 15-17, 20-27 and 29 of co-pending Application No 10/515097. This rejection is respectfully traversed.

Contrary to the Examiner's reasoning, the subject matter of the claims of the co-pending Application No. 10/515097 does not overlap with the subject matter of the claims of the present invention. In the instant-application the glycyrrhizate is not the active substance, rather, propolis is. Moreover, the addition of glycyrrhizate is always as the second auxiliary

co-grinding substance and this is essential to confer the unexpected solubility properties of the co-ground powdered quaternary composition, comprising glycyrrhizate, of the claimed invention in comparison to the corresponding ternary composition without glycyrrhizate. This is not obvious from the claims of the co-pending application.

For at least the reasons noted above, withdrawal of the record rejection of claims 1-11, 15-18, and 20-21, on the ground of non-statutory obviousness-type double patenting as being obvious over claims 1, 6, 9, 10, 11, 15-17, 20-27 and 29 of co-pending Application No 10/515097 and allowance of said claims is respectfully requested.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is hereby earnestly solicited.

Respectfully submitted,

Date: March 12, 2008

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